UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,220	12/18/2001	Caroline Dean	Mewburn	7555

110 7590 06/16/2004

DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,220	DEAN ET AL.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 60-107* is/are pending in the application.

4a) Of the above claim(s) *5-10,66-71,76,77 and 79-106* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 60-65, 72-75, 78 and 107* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 3/26/2004 has been entered.

Claims 1-10 and 60-107 are pending.

Claim 107 has been newly added.

Claims 5-10, 66-71, 76-77, and 79-106 have been withdrawn from consideration as being drawn to a non-elected invention.

2. Claims 1-4, 60-65, 72-75, 78 and 107 are examined in the present office action.

3. Rejections and objections not set forth below are withdrawn.

4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Claim Objections

5. Claims 63 and 64 remain objected to for reading on non-elected inventions, i.e., "or has promoter and/or regulatory function". Correction is requested.

Claims 72-75 and 78 remain objected to for reading on non-elected inventions, i.e., Applicant has not removed references to sequences other than the elected sequences and primer sequences.

Indefiniteness

6. Claim 75 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 75, the recitation of "highly stringent conditions for hybridization" has not been defined. Applicants have not taught the specific conditions that must be used to facilitate hybridization of the probe with the desired nucleic acid sequence. This rejection is maintained for the reasons of record set forth in the Official action mailed 8/21/2003. Applicant's arguments filed 3/26/2004 have been fully considered but they are not persuasive.

Applicants contend that it would be inappropriate to recite the exact conditions for hybridization, owing to the range of conditions that are available to the skilled person. Applicants points to page 26, line 36 to page 27, line 26 of the application for details as to hybridization conditions. Applicants contend the skilled artisan would use the appropriate conditions (paragraph bridging pages 19 and 20).

The Office contends that there are many combinations of reagents that yield "stringent conditions" and that specifically stating the particular conditions for hybridization in the claim removes any ambiguity that arises when simply reciting "highly stringent conditions". In addition, conditions that may be "highly stringent" for one group of people, are not necessarily "highly stringent" for another group.

Written Description

7. Claims 1-2, 60-63, 65, 72-75, and 78 remain rejected and amended claim 64 and new claim 107 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official

action mailed 8/21/2003. Applicant's arguments filed 3/26/2004 have been fully considered but they are not persuasive.

Applicants contend that the instant specification contains sufficiently detailed, relevant identifying characteristics which provide evidence that the applicants were in possession of the claimed invention. Applicants disclose the sequence of the VRN2 cDNA from Landsberg erecta and Columbia ecotypes and allelic/alternatively spliced forms of the same. Applicants contend that the VRN2 sequences are shown to affect physical characteristics of a plant including vernalization response, flowering time, leaf size, shape and shade avoidance. Applicants contend the claimed invention provides a specific structure which is linked to a specific function (page 21, 1st paragraph).

The Office contends that Applicants' claims are drawn to nucleic acids from the VRN2 locus from any plant and yet Applicants only describe nucleic acid sequences from Arabidopsis thaliana, ecotype Landsberg and Columbia. To fulfill the written description requirement for Applicants' broad claims, Applicant is required in part, to disclose sequences from other species of plants. Applicant has not disclosed specific structural features unique to the nucleic acid molecules encoding any VRN2 protein, or unique structural features of the encoded protein. In addition, the physical characteristics that Applicant specifies, are controlled by a host of genes, and are not specific to Applicants' claimed invention.

Applicants contend that the Examiner's assertion that Applicants do not disclose structural, physical or chemical properties for the sequence is unjustified (page 21, 2nd paragraph). Applicants also contend that the disclosure of structural/physical/chemical

properties of VRN2 is provided throughout the specification e.g., page 53; Table 2, page 66; and in Figure 6 (paragraph bridging pages 21 and 22).

The Office contends that the Brief Description of the Drawings for Figure 6, only specifies the putative NLSs, putative acidic activation domain and putative zinc-finger motif, all of which are domains that are not specific to Applicants' invention. The specification, including Table 2, does not specify domains that are specific to Applicants' invention.

Applicants contend that methods of identifying variants are routine in the art. The specification describes how homologues may be obtained from cDNA libraries using hybridization probes (page 22 2nd paragraph).

The Office contends that Applicants have not identified or isolated from Arabidopsis or from any other plant, variants of nucleic acids encoding a VRN2 protein whose function is the same as Applicants' VRN2 protein. Applicants disclose general techniques of molecular genetics, but Applicant has not disclosed by way of example, any variants of the nucleic acid sequences encoding SEQ ID NO:2 from other plants.

Applicants contend that the functional features in the claims do not cover sequences that lack the "proper activity", and activity can and would be routinely determined by the skilled person whenever a potential variant is identified (page 22, 3rd paragraph).

The Office contends that the specified activity is not specific to applicants' invention. For example, regulating flowering time is controlled by a multitude of genes, not just Applicants' invention.

Applicants contend that some variants are explicitly exemplified in the Application (page 22, 4th paragraph).

The Office contends that the exemplified sequences are only from Arabidopsis and are not sufficient to fulfill the written description requirement for Applicants' broadly claimed invention.

Applicants contend that new claim 107 uses language that is closely based on Example 9 of the "Synopsis of Application of Written Description Guidelines" and thus it is Applicants' position that this claim fully satisfies the requirements of 35 U.S.C. §112 , first paragraph (page 23, top paragraph).

The Office contends that Example 9 discloses the isolation of a nucleic acid sequence using specific hybridization conditions and the resulting nucleic acid sequence encodes a protein with a demonstrated specific function, i.e, a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity. Applicants do not disclose a nucleic acid sequence that hybridizes to SEQ ID NO:1 under specific hybridization conditions and has a specific biochemical activity. Applicants only list physical characteristics that the encoded protein allegedly affects, and they do not disclose a specific biochemical activity or assaying the encoded proteins for such activity.

Enablement

8. Claims 1-4, 60-65, 72-75 and 78 remain rejected and claim 107 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for

the reasons of record set forth in the Official action mailed 8/21/2003. Applicant's arguments filed 3/26/2004 have been fully considered but they are not persuasive.

Applicants contend that it is straightforward for the skilled person to use the explicitly provided sequences to identify and obtain related sequences falling within the scope of the claims. Applicants contend that the appropriate techniques for identifying and/or obtaining such nucleic acids are taught in the application. Applicants contend that one skilled in the art would not incur undue burden of experimentation (page 24, 1st and 2nd paragraphs).

The Office contends that the claims read on a multitude of sequences that Applicant has not exemplified. Even though the techniques are known in the art, it would still cause undue trial and error experimentation to screen through the multitude of sequences that are encompassed in Applicants' claims.

Applicants contend that the identity of the VRN2 locus is known and defined by mapping. Applicants contend that the apparently related sequence that appears quite close to the VRN2 locus on chromosome 4 of A. thaliana and shares some sequence similarity with the VRN2 gene, is not the VRN2 gene and should not cause confusion (page 24, 3rd paragraph).

The Office contends that the term "VRN2 locus" is not specific to only one gene. The resolution of mapping as disclosed in Applicants' specification, is not specific to only one gene, and many genes reside at this particular locus. Applicants have also not specified a specific biochemical assay for the VRN2 gene other than the general phenotypic changes that occur when the gene is mutant. The specified phenotypic changes are regulated by many genes and any one of the hundreds/thousands of genes will affect the physical characteristics that are specified in claim 1.

Applicants contend that variants can be obtained and then tested for function (page 25, top paragraph).

Applicants have not specified a particular biochemical assay specific to the VRN2 gene (see above).

Applicants contend that well-known and straightforward techniques are available for identifying the claimed sequences, allowing the skilled person to perform the claimed methods and obtain the claimed sequences with no undue burden (page 25, bottom of middle paragraph).

The Office contends that the claims read on a multitude of sequences that Applicants have not exemplified. Even though the techniques are known in the art, it would still cause undue trial and error experimentation to screen through the multitude of sequences that are encompassed in Applicants' claims.

Applicants contend that amended claim 75 now overcomes the Office's objection that even stringent hybridization conditions do not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe. Applicants contend that the hybridization is not per se the sole identification step (paragraph bridging pages 25-26).

The Office contends that Applicants have not supplied a biochemical assay to specifically identify sequences that encode a protein with the same activity/function as Applicants' VRN2 gene, and as such, positively identifying sequences that hybridize to sequences exhibiting 90% sequence identity to SEQ ID NO:1 would cause undue trial and error experimentation.

Applicants contend that the Bowman et al and Siegfried et al references actually show that CRC and the related family members all show the same function, namely the specification of abaxial cell fate (page 26, middle paragraph).

The Office contends that the "function" as recited by Applicant is a general phenotypic characterization of the CRC family members and that each one has a specific "biochemical function" that cannot be replaced by other family members.

Applicants contend that claims 72-75 and 78 now recite a probe whose sequence represents a region that is at least 90% identical between SEQ ID NO:1 and related sequences and comprises a conserved sequence (page 26, last paragraph).

The Office contends that Applicant is arguing limitations not specified in the claims. The claims do not specify any conserved regions and even using sequences that are 90% identical between SEQ ID NO:1 and related sequences still hybridize with sequences whose function is different than Applicants' VRN2 gene. In addition, Applicants have not specified a specific biochemical assay for their invention as discussed above.

Applicants contend that they need not demonstrate the operability of each and every species covered by their claims and that patentable claims may cover inoperable species (page 27, 1st full paragraph).

Applicants' claims are drawn to a multitude of sequences while Applicants have only exemplified one sequence. Undue trial and error experimentation would be required by one skilled in the art to identify and isolate a sequence with the same biochemical activity as Applicants' VRN2 gene.

See Atlas Powder v. DuPont, 224 USPQ 409, 414 (Fed. Cir. 1984), where a significant number of inoperative embodiments was deemed to indicate an undue amount of experimentation.

Applicants contend that transformation of plants can have variable effects and this is true of any biological system. (Applicants are addressing the Office's indication that transforming plants with heterologous genes produces unpredictable results, as taught by Kano-Murakami et al cited by the Examiner on page 13 of the last office action.) Applicants contend that this is normal and the skilled artisan selects those plants displaying the desired effects and this constitutes the normal amount of experimentation (paragraph bridging pages 27-28).

The Office contends that the issue of undue trial and error experimentation is not just for transforming plants with heterologous nucleic acid sequences. The issue of undue trial and error experimentation encompasses all the procedures that are required for identifying and isolating sequences that Applicant is claiming, not just transforming plants with heterologous nucleic acid sequence. The point of the Kano-Murakami et al reference was to demonstrate that unpredictable results are generated from that particular aspect of the process and given the unpredictable nature of that part of the process taken with all the other steps, undue trial and error experimentation would have been required.

9. Claims 1-4, 60-65, 72-75, 78 and 107 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:1 encoding SEQ ID NO:2, or a polynucleotide with at least 90% sequence identity thereto, and a method for identifying a nucleic acid of SEQ ID NO:1.

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
June 9, 2004

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638